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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/17/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/361,619

Applicant(s)

LOOSMORE ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 8 ~~is/are~~ are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9 and 10 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Serial Number: 09/361,619
Art Unit: 1645

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 09/26/03 (paper no. 19) in response to the non-final Office Action mailed 03/26/03 (paper no. 17).

Status of Claims

- 2) Claims 1 and 7-9 have been amended via the amendment filed 09/26/03.
Claims 1, 2 and 5-10 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the drawings made in paragraph 7 of the Office Action mailed 09/25/01 (paper no. 14) is withdrawn in light of Applicants' submission of formal drawings. These drawings have been approved by the draftsman.

Rejection(s) Withdrawn

- 6) The rejection of claim 9 made in paragraph 11(b) of the Office Action mailed 09/25/01 (paper no. 14) and maintained in paragraph 11 of the Office Action mailed 07/01/02 (paper no. 16) and the Office Action mailed 03/26/03 (paper no. 17) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

- 7) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 15 of the Office Action mailed 07/01/02 (paper no. 16) and maintained in paragraph 13 of the Office Action mailed 03/26/03 (paper no. 7), with regard to part(c) of claim 1, under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein and herebelow.

Applicants point to Table 1A and 1B as listing a large number of strains of *Moraxella*

Serial Number: 09/361,619
Art Unit: 1645

catarrhalis, their origin and the level of expression of the 200 kDa protein. Applicants then point to Table 5 and state that a strain of *Moraxella catarrhalis* strongly expressing the 200 kDa protein is a strain that reasonably would be expected to have the nucleotide sequence having the characteristics of claim 1(c). Applicants submit that 15 strains in Table 5 showing strong expression of the 200 kDa protein possessed a G tract which is three or a multiple of three Gs and 'possess.. an ATG start codon'. Applicants assert that since Applicants have identified the characteristics required for the nucleotide sequence defined in claim 1(c), they were in possession of the nucleotide sequences recited therein. Applicants further allege that the Office asserts, without any justification, that the observation obtained from the genetic analysis regarding one of *Moraxella catarrhalis* that expresses the 200 kDa protein cannot be extrapolated to every other 200 kD protein-expressing strain of *Moraxella catarrhalis*. Applicants state that similar enhancement of transcriptional control are found for other bacterial genes, such as, *N. gonorrhoeae Pilc* gene.

Applicants' arguments have been considered, but are non-persuasive. The genus claimed in claim 1(c) as amended, is not enabled. Figures 4 and 5 depict nucleotide sequences of two strains of *Moraxella catarrhalis*, Q8 and LES-1 respectively, the former having a tract of 9 Gs and the latter having a tract of 3 Gs. These two strains do not qualify as 'strains of *Moraxella catarrhalis* other than strains ... Q8 and LES-1' as now recited in claim 1(c). The nucleotide sequence claimed in claim 1(c) is required to encode an about 200 kDa outer membrane protein; the level of expression, i.e., +, ++ or +++ etc. is irrelevant. One + expressing strains of *Moraxella catarrhalis*, other than 4223, Q8 and LES-1, are not excluded from claim 1(c). The +++ expressers of the 200 kDa protein as depicted in Table 5 are only speculated to have ATG as a 'possible' start codon. There is absolutely no showing that ATG codon, if indeed present, was located at about 80 to 90 bp upstream of the G tract in the 18 strains depicted in Table 5. It is not known which exact strains are included among the 18 strains in Table 5, i.e., whether these 15 strains include or exclude Q8 and LES-1. Applicants are correct in that Table 1A lists and identifies a number of strains of *Moraxella catarrhalis*, many of which are +++ expressers of the 200 kDa protein. However, the non-extrapolatable nature or the unpredictability factor is evident from the data depicted therein in that expressers of the 200 kDa protein do not consistently have, or need not exclusively have 3 Gs, 6 Gs or 9 Gs etc., because strain 4223 listed in Table 1A, is also an expresser of the protein. Applicants have admitted previously that

Serial Number: 09/361,619
Art Unit: 1645

4223 strain of *Moraxella catarrhalis* has a tract of ten G bases and a GTG start codon (see middle paragraph on page 10 of Applicants' amendment filed 03/25/02). For instance, Table 5 shows that at least three strains of *M. catarrhalis* did express the 200 kDa outer membrane protein, yet had 10 (i.e., not a multiple of 3) G nucleotides in the G tract of the gene and a possible GTG start codon, as opposed to an ATG start codon. As is evident from the results shown in Table 5, one cannot predict that every strain of *M. catarrhalis* that is able to express the 200 kDa outer membrane protein at +, or +++ level contains a gene or nucleotide sequence characterized by 3, or a multiple of 3 consecutive G nucleotides **and** an ATG start codon at the specific locations as recited in part (c) of claim 1. The specification in the second full paragraph on page 42 of the instant specification describes that Table 5 represents the results obtained with 24 other strains of *M. catarrhalis*. Table 1A lists much more than 24 strains of *M. catarrhalis*, about 79 of which are indicated in the right column of the Table to be expressers of the 200 kDa protein. However, there is no evidence within the instant specification that a representative number of these more than seventy 200 kDa protein-expressing strains of *M. catarrhalis* from Table 1A (other than 4223, Q8 and LES-1) does indeed carry a nucleotide sequence with the recited structural properties. There is no evidence that nucleic acid molecules from a representative number of these strains have nucleotide sequences with such structural characteristics, and that such molecules were indeed isolated, purified and genetically analyzed, and that Applicants had possession of such sequences at the time of the invention. This is critical in light of the unpredictability evident from the results depicted Table 5, as explained above. Table 5 shows that strains of *Moraxella catarrhalis* having 10 Gs and a CTG start codon in their nucleotide sequence do express the 200 kDa protein. This is *prima facie* evidence that any strain of *M. catarrhalis* other than Q8 and LES-1 expressing the 200 kDa protein would not reasonably be expected to have a nucleotide sequence having the ATG start codon and the G tract at specific locations recited in claim 1(c). Thus, Applicants' own specification provides the justification for the rejection made by the Office. With regard to the number of consecutive Gs in the tract and the presence of CTG or ATG as the start codon being responsible for the expression of an about 200 kDa protein, when one cannot extrapolate the results obtained with one strain of 200 kDa protein-expressing *M. catarrhalis* to another 200 kDa protein-expressing strain, i.e., within the same bacterial genus and species, one of skill in the art would not turn to a heterologous bacterial genus

Serial Number: 09/361,619
Art Unit: 1645

such *N. gonorrhoeae* or its *Pilc* gene. Other than the isolated nucleotide sequences from Q8 and LES-1 strains of *M. catarrhalis* encoding an about 200 kDa outer membrane protein and having 9 and 3 Gs respectively and an ATG start codon, Applicants were clearly not in possession of an isolated nucleotide sequence as recited in claim 1(c) from a representative number of other strains of *M. catarrhalis* containing a tract of 3 consecutive G nucleotides or any multiple thereof (including 30, 60, 90, 120 Gs etc.) at the precise position, as recited therein. The full scope of the claimed invention is not enabled. Due to the lack of evidence, the lack of specific guidance, the breadth of the claims, the lack of working examples enabling the full scope, the demonstrated unpredictability factor as explained above, and the quantity of experimentation necessary, undue experimentation would have been required by one of ordinary skill in the art to reproducibly practice the full scope of the invention. The rejection stands.

8) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 14 of the Office Action mailed 09/25/01 (paper no. 14) and maintained in paragraph 13 of the Office Action mailed 07/01/02 (paper no. 16) and paragraph 12 of the Office Action mailed 03/26/03 (paper no. 17), with regard to part(c) of claim 1, under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 5,808,024 - Applicants' IDS), is maintained for reasons set forth therein and herebelow.

9) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 15 of the Office Action mailed 03/26/03 (paper no. 17) under the judicially created doctrine of obviousness-type double patenting over claims 5-13 of the US patent 5,808,024 ('024) is maintained for reasons set forth therein and herebelow.

Applicants contend that part (c) of claim 1 is amended to clarify that the recited strain of *Moraxella catarrhalis* is other than strains 4223, Q8 and LES-1. With regard to the recitation 'amino acids 25 and 35', Applicants state that amino acid number 1 is the first amino acid encoded by the nucleotide sequence, the recited ATG start codon, and that the amino acids 25 and 35 are the twenty-fifth and thirty-fifth amino acids of the about 200 kDa outer membrane protein of *M. catarrhalis* encoded by the defined nucleotide sequence. With regard to the interpretation of the term 'about' in part (c) of claim 1, Applicants state that the term has been deleted. Applicants agree that Figure 6 of the '024 patent shows the nucleotide sequence of the gene having an open reading frame of the about 200 kDa outer membrane protein of *M. catarrhalis*. Applicants allege that no

Serial Number: 09/361,619
Art Unit: 1645

attempt is made to identify the start codon of the open reading frame, or the portion of the nucleotide sequence which encodes an outer membrane protein. Applicants assert that the strain of *M. catarrhalis* from which the nucleotide sequence of Figure 6 was derived is strain 4223.

Applicants once again allege that Figure 6 of '024 patent with the ATG and GGG areas boxed and highlighted by the Office has not been received and that if it was received, it is 'misplaced'.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion, part (c) of claim 1 still includes the limitation 'about'. Claim 1(c) does not recite or identify any open reading frame. The nucleotide sequence claimed in claim 1(c) is required to encode an about 200 kDa outer membrane protein, and the nucleotide sequence taught by the '024 patent does teach such a nucleotide sequence. The '024 patent does not disclose that what is depicted in Figure 6 originated from strain 4223. In fact, the sentence preceding the one which describes Figure 6 in the last full paragraph in column 2 explicitly states that the nucleic acid molecule encoding the about 200 kDa protein is for strain 4223, **or other strains**. See the last sentence in the fifth full paragraph in column 2. Sasaki *et al.* ('024) did teach a nucleic acid molecule from other *Moraxella* strains other than *M. catarrhalis* 4223, Q8 and LES-1 (see Examples 2 and 9-11). Nothing in the '024 patent indicates that one of the ATG codons in the Figure 6 (provided twice by the Office to Applicants with the codons boxed and highlighted) is NOT the start codon. Figure 6 of the '024 patent shows the nucleotide sequence of the gene having an open reading frame of the about 200 kDa outer membrane protein of *M. catarrhalis*. The nucleic acid molecule encodes an about 200 kDa outer membrane protein. This nucleic acid molecule is what is claimed in claims 1 and 2 of the '024 patent. The nucleic acid molecule of claim 1 includes this nucleotide sequence and is from 'a strain of *Moraxella catarrhalis*' which includes strains other than 4223, Q8 and LES-1. Claim 2 of the '024 patent does not exclude strains of *Moraxella catarrhalis* other than 4223, Q8 and LES-1. In part (c) of claim 1, as amended currently, the recited tract of consecutive G nucleotides of 3 or a multiple of 3 is located in a 'portion' of the nucleotide sequence 'which encodes a portion' of said outer membrane protein between amino acids 25 and 35. Since part (c) of claim 1 does not identify or recite a reference amino acid sequence for one to relate the 'amino acids 25 and 35' to, the numbering of amino acids can start anywhere along the portion of the outer membrane protein. In other words, the numbering of the amino acids in said portion is not definite because the

Serial Number: 09/361,619
Art Unit: 1645

amino acid sequence identifier to which this position or numbering is relative to is not recited in the claim. Therefore, the amino acid numbering in the prior art sequence is considered as starting from the amino acid, i.e., the first amino acid, encoded, for example, by the ATG codon situated at the nucleotide bases 1185-1187 (boxed and highlighted in blue) about 80 bp upstream of the GGG tract, which tract is located at the nucleotide base portion 1262-1264. This GGG tract is located in the nucleotide sequence portion that encodes the portion of the outer membrane protein between amino acids 25 and 35. The rejection stands.

10) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 16 of the Office Action mailed 03/26/03 (paper no. 17) under 35 U.S.C § 102(b) as being anticipated by Sasaki *et al.* (WO 96/34960 - already of record) ('960), is maintained for reasons set forth therein and herebelow.

Applicants note that claims 1, 5, 6, 9 and 10 were rejected previously using Sasaki *et al.* (WO 96/34960) and that the rejection was later withdrawn. Applicants state that it is not known why after withdrawing the rejection in view of the arguments provided, 'the same rejection of the same claims (with the exception of claim 2) based on the same prior art' is made [Emphasis in original].

Applicants submit that the comments made above with respect to the '024 patent apply equally here. Applicants allege again that they did not receive a copy of Figure 6 of WO 96/34960 with certain areas boxed and highlighted. Applicants assert that in common with the '024 patent, WO 96/34960 has only a nucleotide sequence in Figure 6 with no ATG or other start codon or open reading frame identified.

Applicants' arguments have been considered, but are non-persuasive. As is self evident from paragraph 19 of the Office Action mailed 07/01/02, the original prior art rejection was directed to the nucleic acid claimed in the original claim 1(a). The Figure 6 attachment has been promptly supplied and re-supplied to Applicants as a part of the previous Office Actions. The previous rejection was properly withdrawn in light of Applicants' amendments to part (a) of the claim. The new rejection made in paragraph 16 of the non-final Office Action mailed 03/26/03 (paper no. 17) is applicable to part (c) of claim 1. Therefore, it is untrue that the two rejections are 'the same'. Further, it should be noted that what is claimed in claim 1(c) is only a nucleotide sequence. The prior art nucleotide sequence meets the recited structural element 'ATG'. The fourth full paragraph on page 12 of WO 96/34960 identifies the coding sequence of the gene encoding the about 200 kDa outer membrane

Serial Number: 09/361,619
Art Unit: 1645

protein of *M. catarrhalis* and identifies the 'ATG' codon as the start codon. The ATG codon in the top most line of the sequence on page 11/47 of the prior art Figure 6 encodes MET as the first amino acid. The GGG tract is located in the third line on the same page, a part of which forms the codon that encodes the 26th amino acid Val, and the rest of which forms a part of the codon that encodes the 27th amino acid Gly of the protein encoded by the nucleotide sequence. Clearly, the disclosure of WO 96/34960 anticipates the instant claim 1(c). The rejection stands.

11) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 14 of the Office Action mailed 03/26/03 (paper no. 17) under the judicially created doctrine of obviousness-type double patenting over claims 1, 3-7, 9 and 10 of the US patent 6,448,386 ('386) is maintained for reasons set forth therein and herebelow.

12) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 17 of the Office Action mailed 03/26/03 (paper no. 17) under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 6,448,386 - already of record) ('386), is maintained for reasons set forth therein and herebelow.

Applicants state that Figure 6 of the '386 patent is the same Figure 6 as that contained in the 'Sasaki et al '082 patent'. Applicants contend that SEQ ID NO: 2 of the '386 publication is a nucleotide sequence only with no identification of a start codon or an open reading frame. Applicants acknowledge that column 6, lines 54-61 discloses an ATG start codon and state that it is only putative.

Applicants' arguments are considered, but are non-persuasive. Contrary to Applicants' assertion, no '082 Sasaki patent was applied or cited in the last Office Action. It should be noted that what is claimed in claim 1(c) is also only a nucleotide sequence. In claim 1(c), the reference sequence to which 25 to 35 amino acids are relative to is not disclosed. The prior art nucleotide sequence meets the recited structural element, 'ATG'. The Figure 6 description in lines 54-60 of column 6 describes the coding sequence of the gene encoding the about 200 kDa outer membrane protein of *M. catarrhalis* and identifies the 'ATG' codon as the start codon. Columns 47 and 48 of the '386 patent identified Met at position 160, which is viewed as the first amino acid encoded by the ATG start codon. The two amino acids Val and Gly at positions 185 and 186 become the 26th and 27th amino acids encoded by two codons, each containing a part of the GGG codon or tract. Clearly, the disclosure of the '386 patent anticipates the instant claim 1(c). The rejection stands.

Serial Number: 09/361,619
Art Unit: 1645

13) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 18 of the Office Action mailed 03/26/03 (paper no. 17) under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 6,440,425 - already of record) ('425), is maintained for reasons set forth therein and herebelow.

Applicants state that this rejection is repetitious of the prior art rejection in that the same description text is used to support the same argument.

The same rebuttal as provided above for the rejections made using the '386 patent and the WO 96/34960 publication are equally applicable here. The rejection stands.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments, i.e., the submission of new claims.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

14) Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Instant claim 1(c), as amended, includes the limitation: 'a portion of said nucleotide sequence which encodes a portion of said outer membrane protein'. Applicants do not point to a specific part of the specification that provides descriptive support for this phrase. There appears to be no descriptive support for the limitation. Therefore, the limitation in the claim is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the originally filed specification where support for such a recitation can be found.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

15) Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants

regard as the invention.

(a) Claim 1 is vague, indefinite and confusing in the recitation 'a portion of said nucleotide sequence which encodes a portion of said outer membrane protein between amino acids 25 and 35', because it is unclear what is encompassed in this limitation. It is not clear what part of the outer membrane protein is encoded by what part of the nucleotide sequence and where exactly the amino acids 25 and 35 are located. The position of amino acids 25 and 35 is not clear since the claim does not identify any amino acid sequence to which the positions are related to. The metes and bounds of the structure encompassed in the product claimed in claim 1(c) is indeterminate.

(b) Claim 9 is confusing. Claim 9 depends from claim 5, which in turn depends from claim 1. The nucleic acid molecule of claim 1 'consists of' a nucleotide sequence which 'consists of' SEQ ID numbers as recited in part (a) or part (c) of the claim. It is unclear how the host cell of claim 9 containing such a nucleotide sequence that consists of the recited SEQ ID numbers can express 'C-terminal half' of the about 200 kDa protein as opposed to the full length about 200 kDa protein.

(c) Claims 2, 5, 6, 9 and 10, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

16) Claims 1, 2, 5, 6, 9 and 10 are rejected under 35 U.S.C § 102(b) as being anticipated by Aebi *et al.* (*Infect. Immun.* 65: 4367-4377, November 1997 - Applicants' IDS).

Aebi *et al.* taught an isolated gene of *M. catarrhalis* 035E strain (i.e., a strain other than 4223, Q8 and LES-1) that encodes a surface protein having a molecular weight of about 250,000 (i.e., about 200 kDa), cloning plasmid and phage vectors, and a host cell comprising the same. Aebi *et al.* identified the ORF. The nucleotide sequence contained an ATG start codon and a GGG tract wherein the ATG codon was located 89 bp upstream of the GGG tract. The GGG tract was located in a portion of the nucleotide sequence which encodes a portion of the protein at amino acid 32 (i.e., between amino acids 25 and 35). See abstract; Figure 2; page 4369, second full paragraph in right column; page 4367, right column; and pages 4368, 4371 and 4375, left column.

Claims 1, 2, 5, 6, 9 and 10 are anticipated by Aebi *et al.*

Serial Number: 09/361,619
Art Unit: 1645

Remarks

17) Claims 1, 2, 5, 6, 9 and 10 stand rejected. Claims 7 and 8 are allowable.

18) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.